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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,682	04/04/2001	Elena Feinstein	65503-B/JPW/MS	3555

7590

08/02/2005

John P. White  
Cooper & Dunham LLP  
1185 Avenue Of the Americas  
New York, NY 10036

EXAMINER

JOHANNSEN, DIANA B

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 08/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

### **SUPPLEMENTAL EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

2. **Amend the specification as follows:**

Amend the specification as specified in the attached Amendment, which was requested by the examiner on July 20, 2005, and submitted to the examiner by facsimile on July 21, 2005.

**Furthermore, replace the Drawings (Figures 1-6) in the application with replacement Figures 1-6 and new Figure 7, provided by Applicant in the attached Amendment.**

3. It is noted that certain portions of the Amendment submitted July 21, 2005 are not in the format specified in MPEP 1302.04 for facsimile attachments to an examiner's amendment (specifically, 3 paragraphs provided by applicant are in a "marked-up" format, rather than a "clean" format). Accordingly, in the event that the "marked-up" versions are unusable for printing purposes, "clean" versions of the paragraphs submitted by Applicant are set forth below:

Art Unit: 1634

On page 66, lines 1 to 7:

--Table C2 includes the raw measured signals for each gene in 39 hybridizations. P1 are the common control signals. P2 signals represent the measured tissue samples, and are thus more interesting. The genes are sorted by statistical significance with the top gene having the highest score. This is also the order in which they have been incorporated into the predictor (FIGURE 7).—

On page 72, lines 1 to 18:

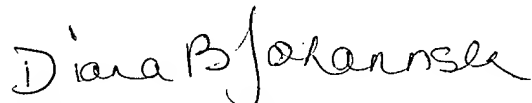
--During the quality control process (section 2), some separation between T1 and Ta samples was noted in the third set of experiments, as well as in global clustering of all 41 profiles (39 normal or non-invasive, plus 2 invasive TCC samples). Therefore clustering of the tumor samples *within the third set only* (FIGURE 7) was pursued. This set contains the largest and most variable collection of TCC samples. A clear differentiation exists between Ta and T1 tumors. One tumor classified as T1/Ta resides within the Ta cluster, but is separated from other Ta tumors. The two invasive tumor samples are in the T1 cluster (one clearly inside, the other outlying). Thus at the level of hierarchical clustering Ta tumors are separated from T1 high-grade tumors.--

Art Unit: 1634

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Diana B. Johannsen  
Primary Examiner  
Art Unit 1634  
July 27, 2005

# Attachment to Supplemental Examiner's Amendment

Jul-21-2005 08:14pm From:cooper&dunham

+212 391 0525

T-199 P.001

F-391

Requested  
DNJ  
7/27/05

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### FACSIMILE TRANSMISSION

\*NEW YORK STATE BAR ADMISSION PENDING

PLEASE DELIVER THE FOLLOWING PAGES

TO : D. Johannsen

COMPANY/FIRM : United States Patent and Trademark Office

FACSIMILE NO. : (571) 273-0744

FROM : John P. White/DNJ

TOTAL NUMBER OF PAGES, INCLUDING COVER PAGE: 15

DATE : July 21, 2005

TIME: \_\_\_\_\_

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DOCKET: 2094/65503-B U.S. SERIAL NUMBER: 09/825,682

MESSAGE: AMENDMENT AFTER PAYMENT OF ISSUE FEE IN RESPONSE TO JULY 20, 2005 TELEPHONE REQUEST BY EXAMINER JOHANNSEN

=====

THE INFORMATION CONTAINED IN THIS FACSIMILE TRANSMISSION IS INTENDED SOLELY FOR THE PERSONAL AND CONFIDENTIAL USE OF THE DESIGNATED RECIPIENT(S) NAMED ABOVE. THIS TRANSMISSION MAY BE AN ATTORNEY-CLIENT COMMUNICATION CONTAINING INFORMATION THAT IS PRIVILEGED AND CONFIDENTIAL. IF THE READER OF THIS MESSAGE IS NOT A DESIGNATED RECIPIENT OR AN AGENT RESPONSIBLE FOR DELIVERING IT TO A DESIGNATED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT YOU HAVE RECEIVED THIS DOCUMENT IN ERROR, AND THAT ANY REVIEW, DISTRIBUTION, OR COPYING OF THIS MESSAGE IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, OR IF UPON READING THIS DOCUMENT YOU HAVE REASON TO BELIEVE THAT THE DOCUMENT WAS INADVERTENTLY SENT TO YOU, PLEASE NOTIFY US IMMEDIATELY BY COLLECT TELEPHONE CALL AND RETURN THE ORIGINAL MESSAGE TO US BY MAIL. THANK YOU.

Docket. No. 65503-B/JPW/DNS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Elena Feinstein and Orna Mor  
Serial No.: 09/825,682 Group Art Unit: 1634  
Filed : April 4, 2001 Examiner: D. Johannsen  
For : METHODS OF DIAGNOSING BLADDER CANCER

1185 Avenue of the Americas  
New York, New York 10036  
July 21, 2005

BY FACSIMILE - (571)273-0744

Commissioner for Patents  
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Alexandria, VA 22313-1450

FACSIMILE CERTIFICATION OF TRANSMISSION  
IN CONNECTION WITH THE ABOVE-IDENTIFIED APPLICATION

Date of Facsimile: July 21, 2005. I hereby certify that this paper including Amendment After Payment of Issue Fee in Response to July 20, 2005 Telephone Request By Examiner Johannsen is being transmitted to the **U.S. Patent and Trademark Office** on the date indicated above by facsimile and is addressed to **U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450 Attn: D. Johannsen.**

Printed Name: \_\_\_\_\_

*Daniel Smith*

Respectfully submitted,

*John E. White*

John E. White  
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Attorney for Applicants  
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Docket No. 65503-B/JPW/DNS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Elena Feinstein and Orna Mor  
Serial No.: 09/825,682 Examiner: D. Johannsen  
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1185 Avenue of the Americas  
New York, New York 10036  
July 21, 2005

BY FACSIMILE - (571)-273-0744

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

AMENDMENT AFTER PAYMENT OF ISSUE FEE IN RESPONSE TO JULY 20,  
2005 TELEPHONE REQUEST BY EXAMINER JOHANNSEN

This Amendment is submitted in response to a July 20, 2005 telephone request from Examiner Johannsen, communicated to Daniel N. Smith of the undersigned's office during which Examiner Johannsen requested amendments to the specification of the above-identified application. Accordingly, applicants submit this Amendment in response to the Examiner's request.

Amendments to the Specification begin on page 2 of this paper.

Remarks begin on page 4 of this paper.

Applicants: Elena Feinstein and Orna Mor  
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Filed: April 4, 2001  
Page 2

Amendments to the Specification

Please add the following paragraph on page 8, line 5 of the specification immediately at the end of the section "BRIEF DESCRIPTION OF THE FIGURES":

--Figure 7: This figure shows relationships between hierarchical clustering of tumor samples (3<sup>rd</sup> Set). The standard Euclidean distance was used as the distance measure between tumor samples.--

Please amend the paragraph beginning on page 66, lines 1 to 7 of the specification as follows:

--Table C2 includes the raw measured signals for each gene in 39 hybridizations. P1 are the common control signals. P2 signals represent the measured tissue samples, and are thus more interesting. The genes are sorted by statistical significance with the top gene having the highest score. This is also the order in which they have been incorporated into the predictor ~~(Table D1)~~ (FIGURE 7).--

Please delete the table on page 66, lines 11 to 34 of the specification.

Please amend the paragraph beginning on page 72, lines 1 to 18 of the specification as follows:

-- During the quality control process (section 2), some separation between T1 and Ta samples was noted in the third set of experiments, as well as in global clustering of all 41 profiles (39 normal or non-invasive, plus 2 invasive TCC samples). Therefore clustering of the tumor samples within the third set only ~~(Table D1)~~ (FIGURE 7) was pursued. This set contains the largest and most variable collection of TCC samples. A clear differentiation exists between Ta and



Applicants: Elena Feinstein and Orna Mor  
Serial No.: 09/825,682  
Filed: April 4, 2001  
Page 3

T1 tumors. One tumor classified as T1/Ta resides within the Ta cluster, but is separated from other Ta tumors. The two invasive tumor samples are in the T1 cluster (one clearly inside, the other outlying). Thus at the level of hierarchical clustering Ta tumors are separated from T1 high-grade tumors.

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Filed: April 4, 2001  
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REMARKS

In a July 20, 2005 telephone conference between Examiner Johannsen and Daniel N. Smith of the undersigned's office, Examiner Johannsen requested certain amendments to the specification of the above-identified application. Specifically, Examiner Johannsen requested that the table on page 66 of the specification be submitted as a figure.

In response, applicants attach hereto as **Exhibit A** seven (7) sheets of Figures 1-6 and new Figure 7.

Further, applicants have amended the specification to include a description of Figure 7 in the Brief Description of Figures section, deleted the table from page 66 the specification, and have amended pages 66 and 72 to refer to Figure 7. Applicants maintain that the above amendments do not create any issue of new matter and are supported, *inter alia*, on pages 66 and 72 of the application as filed.

In conclusion, based on the preceding amendments to specification requested by the Examiner and the remarks, applicants respectfully request prompt issuance of the subject application for which the issue fee was paid on December 15, 2004.

If a telephone interview would be of assistance in advancing issuance of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

Applicants: Elena Feinstein and Orna Mor  
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Filed: April 4, 2001  
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No fee is deemed necessary in connection with the filing of this Amendment. However, if any other fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

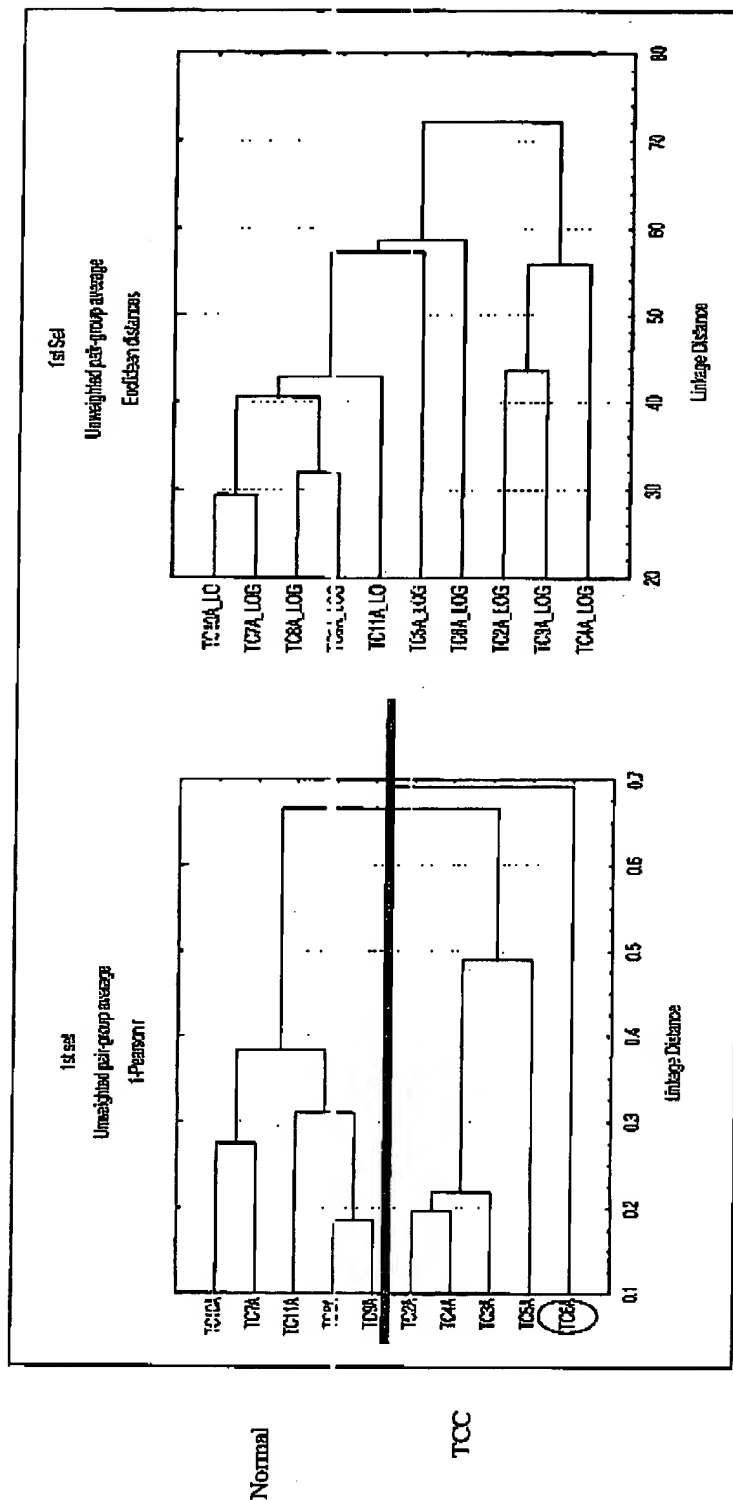


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## EXHIBIT A

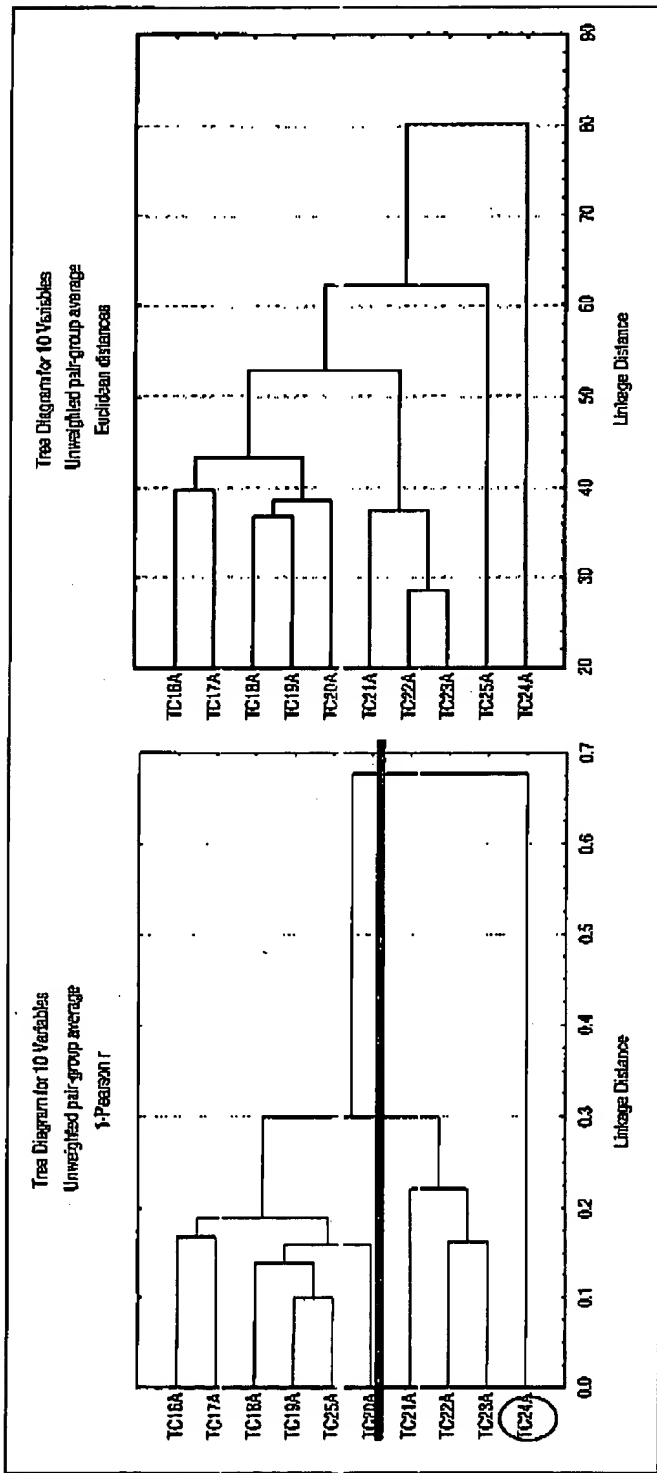
1/7

FIGURE 1

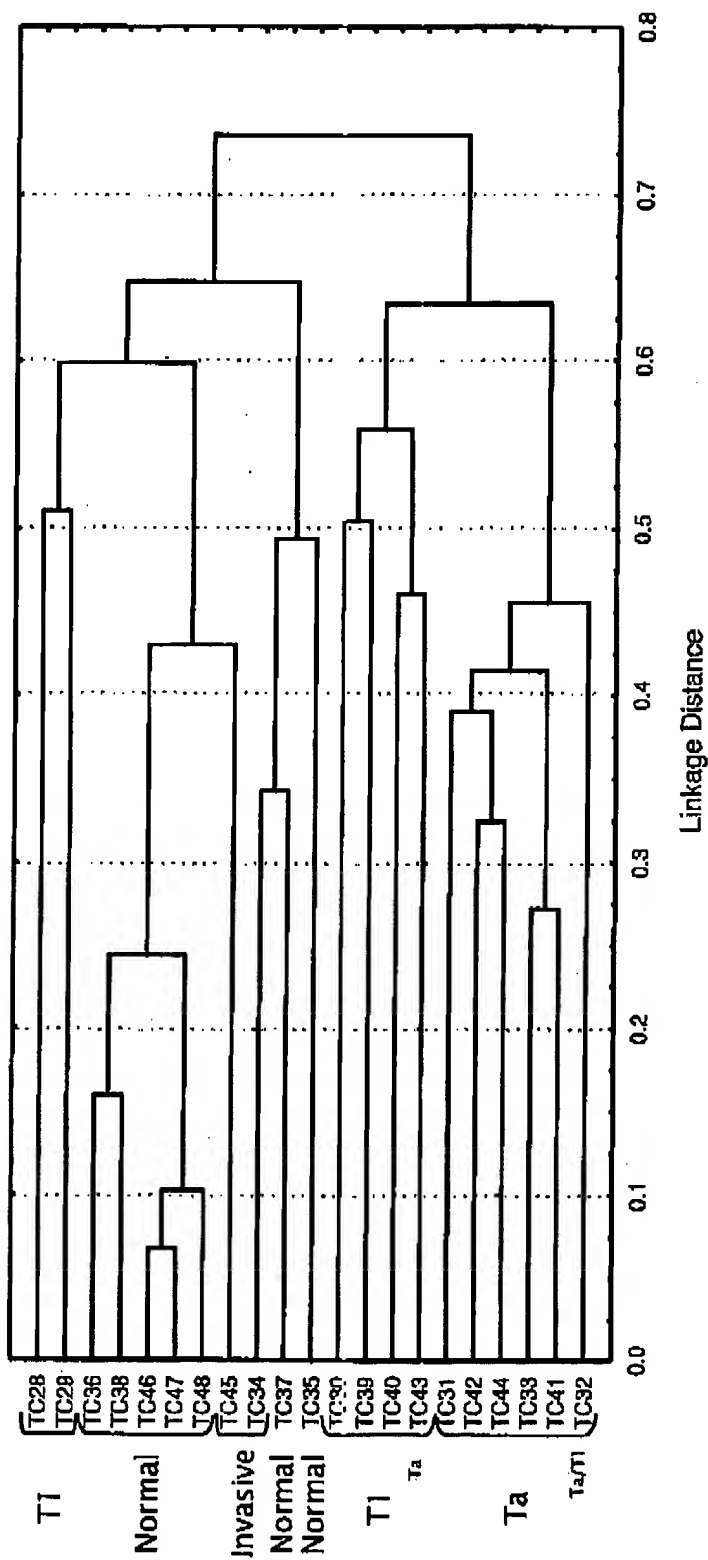


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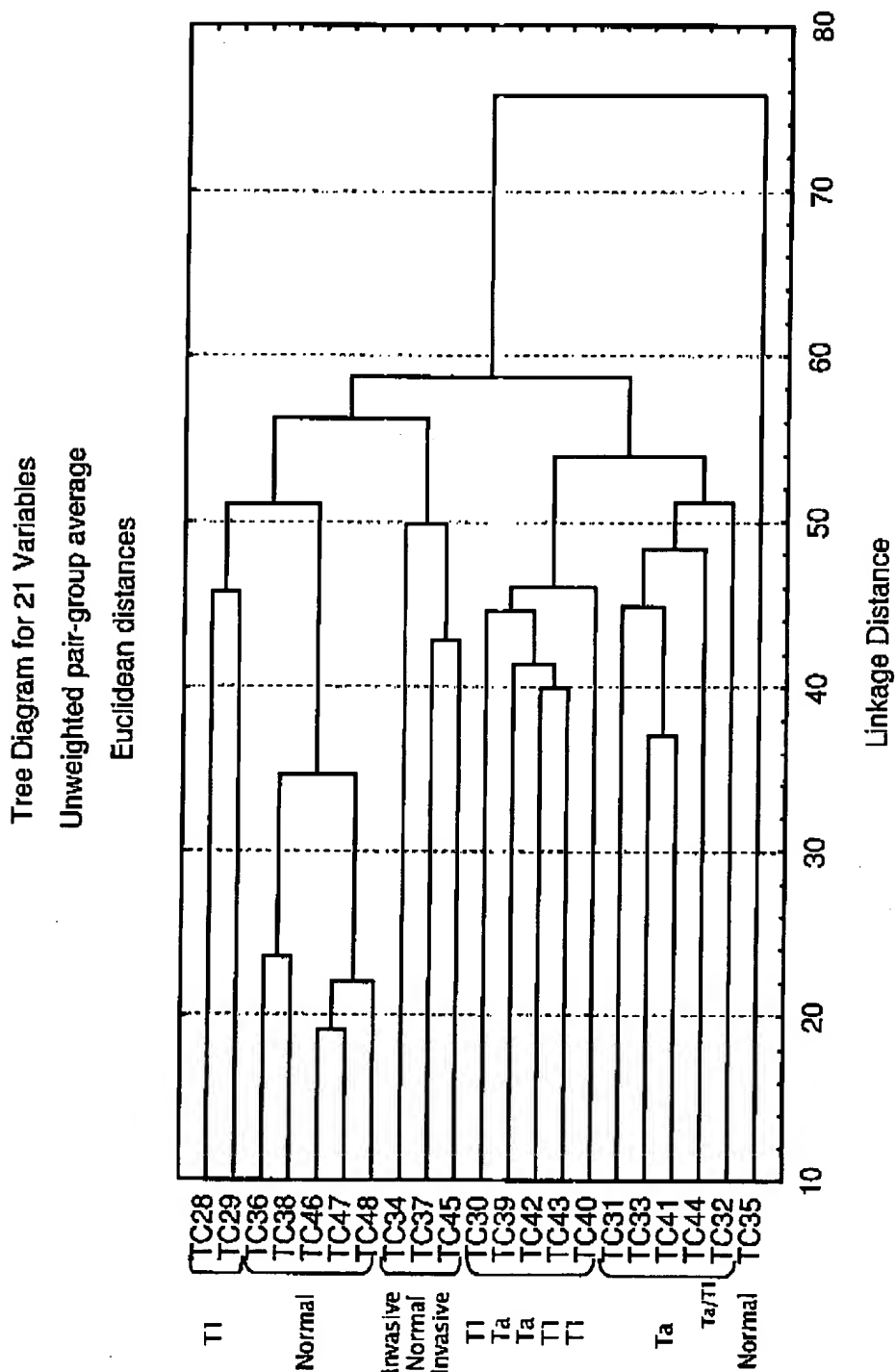
FIGURE 2



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FIGURE 3

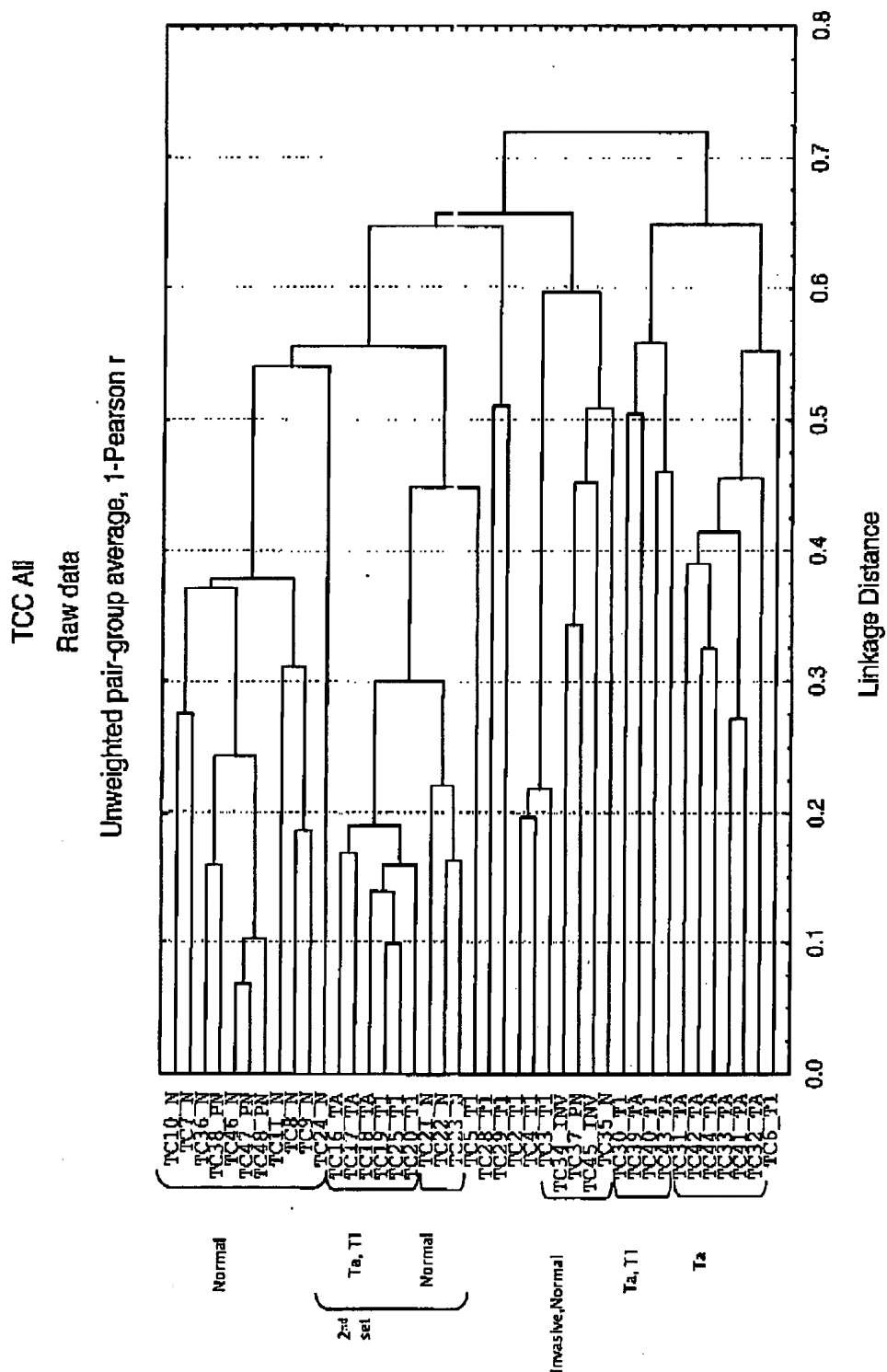


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FIGURE 4

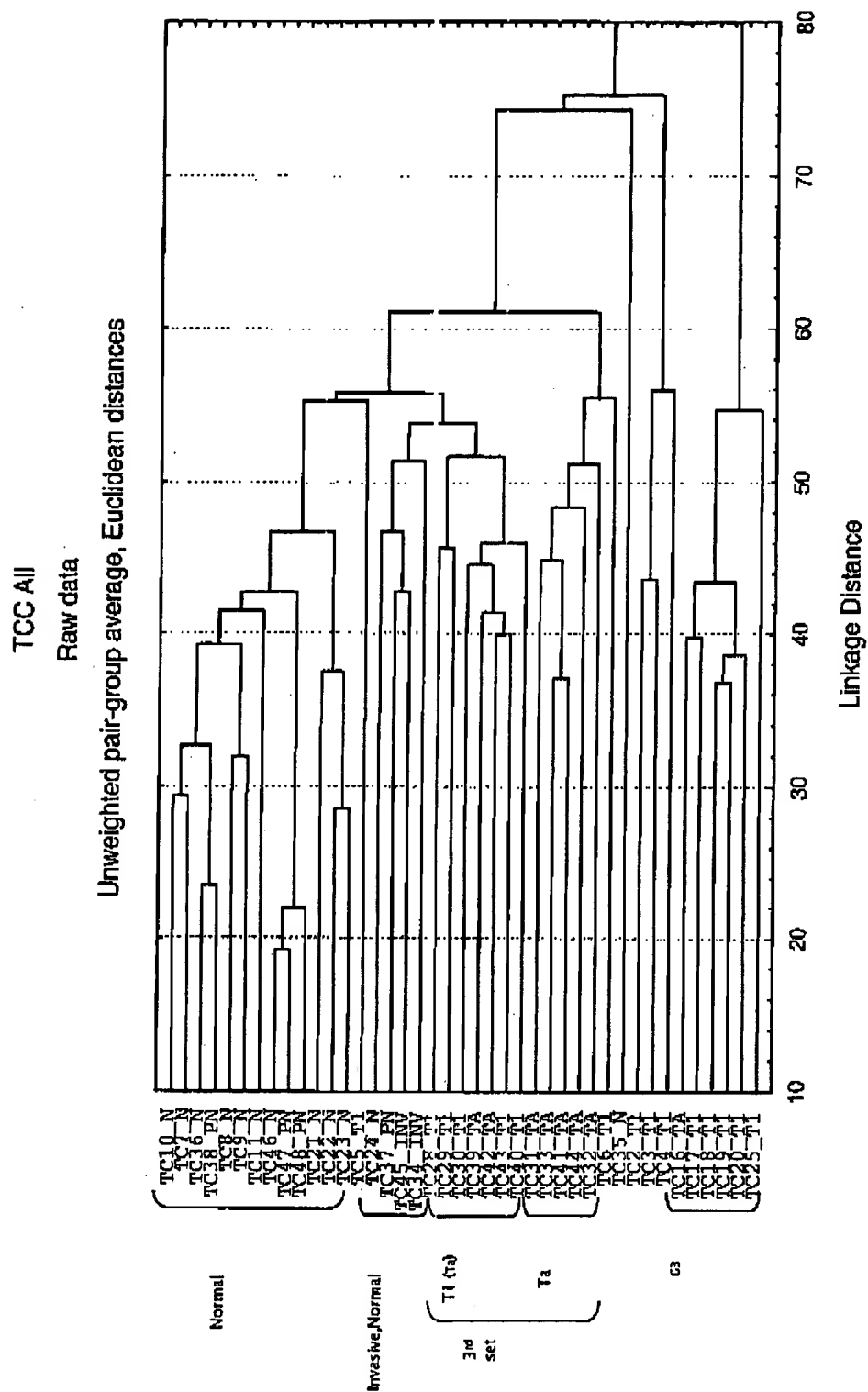




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FIGURE 5



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FIGURE 6



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FIGURE 7

